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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/871,367	05/31/2001	Katrin Kriwet	4-30724A	1754

1095                    7590                    05/09/2002  
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EXAMINER	
KIM, VICKIE Y	
ART UNIT	PAPER NUMBER

1614

DATE MAILED: 05/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/871,367

Applicant(s)

KRIWET ET AL.

Examiner

Vickie Kim

Art Unit

1614

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --***Period for Reply****A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on \_\_\_\_.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

4) Claim(s) 14-41 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_ is/are allowed.

6) Claim(s) \_\_\_\_ is/are rejected.

7) Claim(s) 14-41 is/are objected to.

8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved by the Examiner.

    If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)  The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6

4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_.

## DETAILED ACTION

### ***Response to Arguments***

1. Applicant's arguments with respect to claims 14-38 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 14-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Asakura et al (US 5,385,907) in view of Baumann et al (US 5352671), Treiber et al (US 5,225,403) and Bradley(US 6124362).

Asakura teaches topical preparation including ointments, gel, lotion, containing derivatives of FK-506 including ascomycin as an active ingredient. It teaches that beneficial carrier system which enhances the absorption and solubility of said active ingredient wherein it includes hydrocarbons(e.g. paraffin, petrolatum, etc), lanolin or waxes and absorption –promoting agents such as carboxylic acid(e.g. oleic acid) or esters thereof; see columns 5-6. It also teaches inclusion of inorganic salts such as sodium salt or potassium salt which increases the solubility of said active agent(salts of the active compound); see column 4.

Applicant's claims differ because they require specific species of the active component such as 33-epi-chlloro-33-desoxy-ascomycin in claim 15, and

a carrier component that could be designated to specific carboxylic acid such as lactic acid. Newly added claims 38-41 require cyclic carboxylic acid(e.g. 2-pyrrolidone-5-carboxylate), urea or sodium chloride, respectively.

However it would have been obvious to one of ordinary skill in the art to modify Asakura et al's teaching to accommodate some variations when Asakura is taken in view of Baumann, Treiber and Bradley.

Baumann teaches both ascomycin and it's derivatives(specifically 33-epi---ascomycin) has same physical and chemical properties wherein one could have expected reasonable success of substitution for one to the other; see claims 1-6. It further teaches sodium chloride as an inorganic salt used in process of making ascomycin.

Treiber et al teaches medical utility of ascomycin( FR-900520) and it's medical preparation wherein it suggests urea is suitable carrier to prepare its formulation including topical; see column 7. lines 7-25.

Bradley suggests a topical composition comprising ascomycin(columns 23-24), vehicles(e.g. hydrocarbon, waxes, penetration enhancer(e.g. urea, 2-pyrrolidone-5-carboxylate); column 24.

It would have been obvious to facilitate the solubility and penetration by incorporating enhanced carrier system that is well known in the art as suggested in the references above. One would have been motivated to do so because ascomycin and its derivatives has great industrial value wherein the solubility is most critical problem for manufacturing the medical preparation and the modification of these references could solve the problem.

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same (or similar) ingredients and share common utilities, and pertinent to the problem which applicant is concerning. MPEP 2141.01(a).

### ***Conclusion***

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

5. All the claims are rejected.

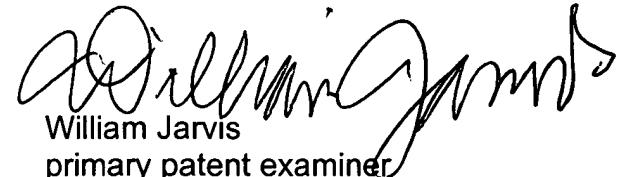
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is

assigned are 703-746-3165 for regular communications and 703-746-3165 for  
After Final communications.

Any inquiry of a general nature or relating to the status of this application or  
proceeding should be directed to the receptionist whose telephone number is  
703-308-1235.

Vickie Kim,  
Patent examiner  
May 6, 2002  
Art unit 1614



William Jarvis  
primary patent examiner